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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,829	09/09/2003	Nikolai M. Krivitski	86017.000037	1750
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Stephen B. Salai, Esq. Harter Secrest & Emery LLP 1600 Bausch & Lomb Place Rochester, NY 14604-2711			EXAMINER  PANI, JOHN	
			ART UNIT 3736	PAPER NUMBER
			NOTIFICATION DATE 02/25/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

bsalai@hselaw.com  
coffen@hselaw.com

### Office Action Summary

**Application No.**

10/657,829

**Applicant(s)**

KRIVITSKI ET AL.

**Examiner**

JOHN PANI

**Art Unit**

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14, 16-22, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 16-20, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings were received on 10/14/2009. These drawings are accepted.

### ***Specification***

2. The amendments to the specification were received on 10/14/2009. These amendments are accepted.

### ***Claim Objections***

3. Claims 14, 20, and 29 are objected to because of the following informalities: In line 6 of claim 14 it is suggested to replace "passing the indicator" with --passing an indicator--. In line 3 of claim 20 it is suggested to replace "a blood flow rate" with --the blood flow rate--. Further, it is suggested to italicize each letter representing a variable in claim 20 in order to clarify the claim. In line 5 of claim 29 it is suggested to replace "passing the indicator" with --passing an indicator--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 20 recites "method of Claim 14, wherein the calculated blood flow rate is described by a relationship  $Q = (k(T_b - T_i) * V(1-a))/S$ , where Q is a blood flow rate, k is a coefficient related to thermal capacity of a measured flow and the indicator,  $T_b$  is a temperature of a measured flow prior to injection of the indicator,  $T_i$  is a temperature of the indicator prior to entering the measured flow, V is a volume of the indicator, S is an area under a temperature versus time curve resulting from a mixing of the indicator and a is a portion of the indicator passing through the terminal port". The claim is indefinite, because it is unclear how this cited limitation is related to the limitations delimiting the "method of claim 14". Particularly, it is unclear whether, for "the calculated blood flow rate" to be "described by a relationship", the claim requires that some or all of the various variables detailed in the relationship are actually measured, etc. during the "method of claim 14" and then passed through the particular relationship, or whether "the calculated blood flow rate" would merely provide a value which could be provided by an appropriate selection of the various variables (i.e. be "described by a relationship"). Because this latter interpretation is the broadest reasonable interpretation, it has been applied herein.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 14, 17, 19, 20, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,089,103 to Smith ("Smith").

9. Smith teaches:

In reference to Claim 14

A method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) to pass a portion of the guide wire through a terminal port ("distal opening") of the indicator lumen; passing the indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); and calculating the blood flow rate as a function of passage of the indicator through the terminal port (col. 4 lines 20-40; note that because the transit time is used to calculate the flow rate, and the passage of indicator through the terminal port is used to determine the transit time, the blood flow rate is calculated as a function of its passage through the terminal port).

In reference to Claim 17

The method of claim 14 (see above) further comprising passing the indicator through the indicator lumen to contact a portion of the guide wire (col. 4 lines 34-37).

In reference to Claim 19

The method of claim 14 (see above) wherein calculating the blood flow rate comprises compensating for a volume of the indicator passing through the terminal port (for example, by noting when the volume is displaced using the pressure signal or temperature signal).

In reference to Claim 20

The method of claim 14 (see above) wherein the calculated blood flow rate is described by a relationship  $Q = (k(T_b - T_i) * V(1-a))/S$ , where Q is a blood flow rate, k is a coefficient related to thermal capacity of a measured flow and the indicator,  $T_b$  is a temperature of a measured flow prior to injection of the indicator,  $T_i$  is a temperature of the indicator prior to entering the measured flow, V is a volume of the indicator, S is an area under a temperature versus time curve resulting from a mixing of the indicator and a is a portion of the indicator passing through the terminal port. (Note: This limitation has been interpreted to essentially require that for any calculated flow value, this flow value could be obtained by choosing appropriate values for the variables in the cited relationship. This interpretation has been determined to be suitable because the claim does not positively tie the various variables in the relationship to the method of claim 14 in a way that the listed variables have a physical relationship to the method. In other words, the current wording of the claim essentially makes the variables abstract values

which could have any value, and the claim does not require that the calculating step uses the claimed relationship to determine the blood flow rate).

In reference to Claims 28 and 29

The method of claim 14 (see above) further comprising sensing the indicator intermediate the terminal port and the injection port (see Fig. 3, the sensor 4 is located intermediate the terminal port and the injection port at least in a direction orthogonal to the longitudinal axis of the catheter 14).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith as applied to claim 14 above, and further in view of US Pat. No. 5,221,256 to Mahurkar ("Mahurkar").

In reference to Claims 16 and 18

Smith teaches the method of claim 14 (see above) and passing the guide wire through the indicator lumen to increase a flow of the indicator through the injection port (as its presence would increase flow through these compared with a situation in which it was not there) but does not explicitly teach a reduced cross sectional area of the indicator lumen. Mahurkar teaches (see Fig. 4) a catheter with a fluid injection lumen

with multiple ports (21, 22). The injection lumen tapers and has a reduced cross-sectional area at its tip. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Smith by making the catheter with a similar tip and lumen configuration so that the distal tip would be more flexible and atraumatic as implicitly taught by Mahurkar.

### ***Response to Arguments***

12. Applicant's arguments, see pgs. 8-9 "Drawings", filed 10/14/2009, with respect to Figures 17 and 18 have been fully considered and are persuasive. The objection of 7/15/09 has been withdrawn.

13. Applicant's arguments, see pg. 9 "Specification", filed 10/14/09, with respect to the paragraph [0038] and [0142] of the specification have been fully considered and are persuasive. The objection of 7/15/09 has been withdrawn.

14. Applicant's arguments, see pg. 9 "Claim Rejections under 35 U.S.C. 112", filed 10/14/09, with respect to claim have been fully considered and are persuasive. The rejection of claim 19 of 7/15/09 has been withdrawn.

15. Applicant's arguments with respect to the rejection of claim 20 under 35 U.S.C. 112, second paragraph have been considered but are moot in view of the new ground(s) of rejection.

16. Applicant's arguments, see pgs. 12-14, filed 10/14/09, with respect to claim 14 and its dependents as being unpatentable over Webster have been fully considered and are persuasive. The rejection of 7/15/09 has been withdrawn.

17. Applicant's remaining arguments filed 10/14/09 have been fully considered but they are not persuasive. In reference to Applicant's assertion that, with regard to Smith, there is "no disclosure of compensating for, or in any way distinguishing passage of the injected bolus through a terminal port in Smith's calculations....Smith does not quantify or otherwise distinguish the amount of saline expelled through the distal opening from the amount of saline expelled through the side holes 16a, 16 in calculating the flow parameter. Because this value is not quantified or distinguished in the disclosed calculation, Smith does not calculate its flow parameter as a function of passage of an indicator through a terminal port", the Examiner notes that the claim does not require distinguishing and quantifying the amount of saline passing through the side ports and the distal port, but merely "calculating the blood flow rate as a function of passage of the indicator through the terminal port". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Because, as noted above, Smith discloses that the blood flow rate is calculated as a function of the passage time of the indicator, and this is a function of the indicator's passage through the distal port (because the passage time is a function of the start of flow and the time at which the temperature signal reaches the sensor), the Examiner submits that Smith does teach the limitation as claimed.

***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 2/17/10

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736

